LUNCHEON SPEECH TO WARBURG DILLON REED
ON GENERIC DRUGS
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I want to talk about two issues of importance to you – a Medicare drug benefit and the Waxman-Hatch Act. But before I do, I want to talk about Congress.

Memorial Day marks the beginning of the end of the congressional calender. As you probably know, the 106th Congress has accomplished very little when it comes to health care. This has nothing to do with lack of resources. In the past, Congress faced huge budget deficits, but we acted decisively to expand health care, combat AIDS and cancer, and clean our air and water.

Today, we are in the midst of a period of tremendous prosperity, but Congress is incapable of delivering the goods. Today, what we lack on the Hill is leadership.

Sometimes I feel like we're trapped in the old joke that, if "pro" is the opposite of "con," the opposite of "Congress" must be — "progress."

I. PROPOSALS FOR MEDICARE DRUG COVERAGE

This lack of leadership will determine whether or not we enact a Medicare drug benefit this year.

As you probably know, congressional Democrats and the Administration have focused on this goal for the past two years. Medicare provides essential health care to millions of senior citizens. But Medicare is clearly missing one critically important benefit— comprehensive prescription drug coverage.

When we enacted Medicare in the 1960s, drugs were not nearly as indispensable as they are today. But the program has lagged behind modern medicine. Today, over 30 percent of seniors have no prescription drug coverage at all, and drug costs are the highest out-of-pocket expenses many seniors have.

Congress tried to enact coverage in the past, in 1988 and in 1994. Our recent effort has stemmed from investigative reports prepared by myself and other House members which document the brand-name industry's price discrimination against seniors. These reports show that drug companies charge many seniors more than double the price that the Federal government pays for the same drugs.

That's because they lack the collective buying power of the government or an HMO behind them. They are on their own. And the high drug prices make it impossible for them to afford their medicines. Our most vulnerable citizens, in greatest need of medicines, must choose between buying their drugs or their food. In a country as prosperous as ours, this is intolerable.

We can solve this problem by ensuring drug coverage and by preventing price discrimination. That's why I have cosponsored a bill (H.R. 1495) that would establish a prescription drug benefit for all Medicare beneficiaries. I am also supporting legislation (H.R. 664) which would end the intolerable price discrimination that many seniors face every day.

For two years, congressional Democrats and the Administration have been arguing for Medicare drug coverage. Our proposal calls for a universal, voluntary drug benefit. All drugs would be covered and the benefit would be administered by the private sector. Medicare would have state-of-the-art drug utilization review and confidentiality. Poor seniors would have their premiums and cost-sharing covered. And generic drugs would be a key to high-quality, cost-effective pharmaceutical care.

A. GENERICS IN MEDICARE

Let me talk a little more about this last point. I know there's interest in emphasizing generic drug utilization under any Medicare drug benefit. I think this is very important.

Generic utilization could -- and should -- increase significantly. Today, roughly 40 percent of all prescriptions are dispensed as generics. The best estimates suggest that rate should be as high as 60 percent. This is extremely important when you consider that scrips dispensed as brand-names are, on average, more than twice as expensive as a generic-filled scrip.

To expand generic utilization, the Democratic Medicare coverage proposal relies on private sector benefit providers, like pharmacy benefit managers (PBMs), to use formularies and generic drugs to hold down costs while maintaining quality care.

But we haven't stopped there. Congressional Democrats are aggressively developing ways of encouraging generic drug use. Senator Tim Johnson has a bill (S.2501, "The Generic Pharmaceutical Access and Choice for Consumers Act of 2000") that focuses on Federal health programs. Congressman Pallone has a bill I consponsored that blocks States from contradicting the FDA's judgement that a generic is therapeutically equivalent to a brand-name drug. And Congresswoman Meek continues to push for maximum generic utilization in Federal Employee Health Benefit (FEHBP) plans.

B. MEDICARE "GENERIC REBATE" UNLIKELY

So we are pushing for generic drug incentives. But now, let's talk about disincentives – namely, the possibility of a Medicare generic drug rebate. At the moment, I don't regard this possibility as very likely.

When we created the Medicaid drug rebate program in 1990, we wanted to ensure the Federal government could act as a prudent purchaser of prescription drugs. As you all know, this was accomplished through a "rebate" on all drug purchases.

Because branded drug prices were -- and still are -- increasing much faster than inflation, we also created a rebate which protected the Federal government from skyrocketing prices. Today, branded companies must give Medicaid a dollar-for-dollar rebate for any increase in their drug prices which exceeds the rate of inflation (CPI).

We didn't adopt this rebate for generic drugs because, at the time, generic prices generally didn't rise faster than inflation. By and large, they still don't. They have always been more affordable than the branded drugs – and they still are today.

But we did include a flat percentage rebate on generic drugs. And there are concerns that this approach may be taken for a Medicare drug benefit.

If you look at the proposals that the Democrats and the Administration have advanced for Medicare drug coverage, none of them take the approach of rebates. We would rely on private benefit providers like PBMs, which historically have done everything they can to maximize generic utilization -- through lower copayments or patient counseling. So I would be very optimistic about the beneficial impact on the generic drug industry of the kind of Medicare drug coverage we are seeking.

C. UNCERTAIN PROSPECTS FOR MEDICARE DRUG BENEFIT

That's the good news. The bad news, I fear, is that despite the enormous effort that congressional Democrats and the Administration have made, I doubt Congress will be able to enact a comprehensive Medicare drug benefit this year.

I say this despite the intense focus and publicity generated in the past two years by myself and other congressional Democrats on the brand-name industry's price discrimination against seniors. I say this despite our two years of work and arguments for Medicare drug coverage.

The public has responded. There has been an outpouring of personal stories and anger from seniors and their families over unfair brand-name drug pricing. They want Medicare drug coverage and they want it now.

But, the House Republican leadership has ignored them. It was just last month that they unveiled their very first proposal – a proposal that doesn't even come close to meeting the needs of poor and middle-income seniors.

I've been in Congress for 25 years, I was chairman of the House Health and Environment subcommittee for 14 years, and before that I was chairman of the Health Committee in the California State Assembly, and I can tell you that if you get in the game after the two-minute warning, you shouldn't expect to accomplish a thing.

That's the bad news. But there's always the hope that, after November, Congress may be in a better position to get down to business and enact a Medicare drug benefit.

II. WAXMAN-HATCH: PROSPECTS FOR REFORM?

Let me turn to our second issue -- the Waxman-Hatch Act, or as my colleague Senator Hatch prefers, the Hatch-Waxman Act.

The success of the Act has truly exceeded my expectations. Generic drugs save billions of dollars in health care expenditures every year. At the same time, the brand-name drug industry is the most profitable industry in the world, and has tripled its research spending in the past ten years.

The key to this success is the Act's careful balance between promoting innovation and ensuring consumer access to affordable medicines. On one hand, there are fair standards for generic drug approvals. On the other, there are fair standards for granting prescription drug patent term extensions.

Notwithstanding this success, I know there is continuing interest in revising the Act. Senator Hatch has been meeting with the brand-name and generic industries. I have also consulted with both industries, the Administration and — most importantly — with consumer and patient groups.

It remains to be seen whether consensus can be reached on positive reforms. On numerous occasions, I have publicly emphasized that any revisions to the 1984 Act must be made in the same spirit and to the same effect as the original statute. Senator Hatch has said much the same.

I would strongly oppose any proposals which would upset the existing balance of commercial and public interests sustained by the Waxman-Hatch Act. Before anything, all of the interested parties should recall the Hippocratic admonition, "First, do no harm."

I doubt Congress can tackle the complex issues of Waxman-Hatch before November. But here are some specific issues which I feel must be addressed if the Waxman-Hatch Act is revisited.

A. GENERIC BIOTECH DRUGS

First, there's the need for generic biotech drugs. In the next few years, a number of blockbuster biotech drugs will come off patent. The first opportunities for generic competition will arise. But today, the law does not provide an expedited way of approving generic biotech drugs.

In 1984, the biotechnology industry was in its infancy. Today, a "generic biotech drugs pathway" -- comparable to the abbreviated approval pathway for conventional drugs -- is urgently needed.

B. 180-DAY EXCLUSIVITY

Second, we must revisit the awarding of 180-days of exclusivity to the first generic drug on the market. Implementation of this Waxman-Hatch provision has been complicated by judicial decisions undermining the FDA's regulations.

This exclusivity may also be subject to abuse. The Federal Trade Commission is currently adjudicating the $40 million annual agreement between Hoechst and Andrx to defer marketing of a generic Cardizem.

I think we should reevaluate the significance of the 180-day exclusivity as an incentive for generic companies to market their products. For some companies and some products, it may be highly important. But for others, it may not. We should see what the experience of the past 17 years tells us.

C. THERAPEUTIC EQUIVALENCE

A third issue is stopping the brand name industry's political efforts to undercut FDA's generic drug approvals. When FDA finds a generic drug is as safe and effective as its brand name competition, the States have no reason to second-guess that scientific judgement. That is especially true when they are being lobbied to do so to protect brand name monopolies.

Just this week, Time magazine ran a piece on DuPont's "rear-guard" actions in States to block generic competition. I think FDA put it best when they said bluntly that the generics are safe and accused DuPont for "stoking false fears."

D. "EVERGREENING" DRUG PATENT LISTINGS

Another issue of concern is what brand name patents should be listed in the FDA Orange Book. As you know, generic companies must certify the patent status of the products they want to market.

But when brand name companies list patents for everything from legitimate active ingredient patents to patents for formulation, shape, color and other nonessential features, they are throwing up regulatory roadblocks to generic drug approvals.

Generic companies should not have to certify the status of these kinds of patents. These patents do not reflect innovation or product quality. They are only meant to hinder competition and lay the foundation of litigation.

E. LOBBYING FOR PATENT EXTENSIONS

Finally, we must stop — once and for all — the political efforts to obtain patent extensions benefitting a few at the expense of the many. I am talking, of course, about lobbying efforts to secure special patent extension for drugs like Claritin.

Claritin had over $2 billion in sales last year. It has enjoyed a full patent term and a patent extension under the Waxman/Hatch Act. It is ripe for competition and patients are entitled to lower prices.

The GAO should complete its investigation any day now on Claritin's approval. We will know shortly just how legitimate a claim Schering Plough has to yet another patent extension.

F. COLUMBIA UNIVERSITY PATENT EXTENSION

Let me conclude with a late-breaking example of the dangers of undercutting the Waxman-Hatch Act. Last week, the news broke that Columbia University has a biotech process patent extension hidden in the
Senate Agriculture appropriations bill. Apparently, Senator Gregg of New Hampshire, the proponent of the patent extension, is a Columbia alumnus.

This fly-by-night patent extension is bad policy and upsets the balance of the Waxman-Hatch Act. The biotech industry is opposed and so is the Administration. The proponents are also misrepresenting the intent of the Act. This should die a quick legislative death.

Perhaps most importantly, this demonstrates why revisiting the Waxman-Hatch Act must be done responsibly, openly and comprehensively. Columbia University is just the latest party willing to upset the apple cart for their private gain – don't think they'll be the last.

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